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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,113	10/23/2001	Eric K. Engelhard	A-70970/RMS/DCF	3901

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,113	ENGELHARD ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8, 9, 20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendments and Arguments

1. Claims 8, 9, 20 and 21 are pending.

Claims 1-7 and 10-19 have been cancelled.

Claims 8 and 9 have been amended.

Claims 20 and 21 have been added.

Claims 8, 9, 20 and 21 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

3. The rejection of claims 8 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants' amendments to the claims and their arguments.

Claim Rejections - 35 USC § 103

4. The rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 6,245,562 (filed May 28, 1996), and further in view of Harlow and Lane

(Antibodies: A Laboratory Manual, pages 139, 174-177, 215, 216, 553, 555-559, Cold Spring Harbor Laboratory, New York, 1988) is withdrawn.

New Grounds and Maintained Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claims 8, 9 and newly added claims 20 and 21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue the new claims limit the scope of the organic compounds and methods for screening for bioactive agents are presented in the application as filed, see page 5, 2nd paragraph of Remarks filed April 28, 2005. In support of the later assertion Applicants have pointed out specific sections of the specification. In conclusion Applicants state that "[c]andidate agents are described throughout the application as filed..." and "a person of ordinary skill in the art would know that any organic compound could be used in the claimed methods." These arguments and points of view have been carefully considered, but found to be unpersuasive.

First and foremost Applicants are reminded that the instant rejection is a 112, 1st paragraph, written description rejection and not an 112, 1st paragraph, enablement rejection. Consequently, most of the arguments presented in the Remarks are not

commensurate in scope. Applicants are reminded that the ability to screen for the bioactive agents and the ability to implement said agents in a method does not support a showing of possession of a plethora of bioactive agents.

While Applicants have amended the claims to define the bioactive agent as an organic compound with a specific molecular weight this information does not absolve the instant rejection. Applicants' attention is directed to the Official Gazette of January 30, 2001. Established therein is the fact that the written description required for a claimed genus is satisfied through sufficient description of a representative number of species, see column 1, section 2 of 1242 OG 174. Applicants list a number an exhaustive listing of candidate agents however there is insufficient correlation between function and structure or a combination of such identifying characteristics sufficient to show Applicants were in possession of the claimed genus. As set forth in the first action of the merits (FAOM) mailed December 28, 2004 the skilled artisan cannot envision the detailed structure of each and every molecule that could possibly be considered an organic compound bioactive agent and conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The product itself is required. Applicants have not fully described bioactive agents with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

For the reasons set forth above and already of record the written description rejection is maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 8, 9, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2002/0119463 A1 (filed July 30, 2001). The disclosure within the patent application publication is regarded as prior art because SEQ ID NO: 53 and 54 are not of record in CIP applications, which Applicants' request priority.

Sequence 75 is a polynucleotide sequence that shares 98.5% sequence homology with Applicants' SEQ ID NO: 54, see attached database sheets. The polynucleotide sequence encodes a prostate cancer protein regarded by the Examiner as a cancer associated protein. The patent application publication discloses a method of screening a plurality of molecules or compounds such as mimetics, peptides, transcriptions and repressors, see page 2, section 0012. The publication also describes screening assays in which neutralizing antibodies capable of binding the protein specifically competes with a test compound capable of binding to the protein, see page 7, section 0082 and page 146, claim 17, c. The antibodies read on Applicants' candidate bioactive agent. It is art known that organic compounds are those molecules that contain at least carbon and hydrogen. This group comprises proteins, which are a group of complex organic macromolecules. Moreover, antibodies are a complex of glycoproteins. Accordingly, the candidate bioactive agent, which is an organic compound, reads on the antibodies, as well as the peptides and mimetics of the disclosing prior art. "Molecules or compounds identified by screening may be used in a model system to evaluate ...toxicity, diagnostic, or therapeutic potential.", see page 7, section 0082. It is within the Examiner's purview that this method reads on Applicants' screening methods. Given the disclosed polypeptide is a prostate cancer protein is regarded as a carcinoma associated protein possessing the bioactivities listed in claim 21. Absent evidence to the contrary the taught bioactive agent has a molecular weight less than about 2,500 daltons.

Claim Rejections - 35 USC § 103

8. The rejection of claims 8, 9, 20 and 21 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 6,245,562 (filed May 28, 1996), and further in view U.S. Patent Application Publication number 2002/0119463 A1 (filed July 30, 2001).

U.S. Patent #6,245,562 teaches an antibody directed to a purified MUM-2 protein (the same as the protein encoded by SEQ ID NO: 54) and capable of specifically recognizing the Applicants' protein and subsequently binding that protein. It is art known that organic compounds are those molecules that contain at least carbon and hydrogen. This group comprises proteins, which are a group of complex organic macromolecules. Antibodies are a complex of glycoproteins. Accordingly, the candidate bioactive agent, which is an organic compound, reads on the antibodies of the patent. The patent does not teach a method of determining the effect of the candidate agent to the CA protein. Absent evidence to the contrary the taught bioactive agent has a molecular weight less than about 2,500 daltons.

However, the patent application publication teaches a method of screening a plurality of molecules or compounds such as mimetics, peptides, transcriptions and repressors, see page 2, section 0012. The publication also describes screening assays in which neutralizing antibodies capable of binding the protein specifically competes with a test compound capable of binding to the protein, see page 7, section 0082 and page 146, claim 17, c. "Molecules or compounds identified by screening may be used in a model system to evaluate ...toxicity, diagnostic, or therapeutic potential.", see page 7, section 0082. It is within the Examiner's purview that this method reads on

Applicants' screening methods capable of determining the effect of the candidate bioactive agent on the bioactivity of the CA protein. The disclosed polypeptide is a MUM1 (multiple myeloma oncogene 1) also known as an IRF4 (interferon regulatory factor 4), a carcinoma associated protein the same as Applicants' protein encoded by SEQ ID NO: 54. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both the patent and patent application publication to assay for antigen/antibody specificity, effect of antibody on CAP, recognition of antigen determinants and implication of the antigen and antibody in diagnostics or other immunological techniques. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the both references that screening for antibodies is routine and further precipitated by establishing information regarding an antigen, such as potential marker for cancer which could reveal knowledge in the areas of diagnosis and antigen characterization.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
06 July 2005